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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/797,374 | 03/10/2004 | Jeffrey O. Phillips | 04242350 | 4467 |

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| EXAMINER | |
|---|---|
| CHANG, CELIA C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1625 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 07/14/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/797,374 | PHILLIPS, JEFFREY O. | |
| | Examiner | Art Unit | |
| | Celia Chang | 1625 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *237-289* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *237-289* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

**1.** This application is a RCE of SN 10/797,374.

Claims 237-289 (please note that claims 291-299 have been renumbered as 281-289) are pending.

**2.** Claims 237-289 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is well recognized in the art that blood concentration of a drug after an oral dose is a dose dependent process. The specification provided a composition comprising examples I.A-I.G3 specific composition and the description that such compositions would be useful to provide a blood concentration measurements as described on page 19 bout 0.1 μg/ml within about 15 minutes after administration of the composition. Such results can support the operability of these exemplified compositions wherein the buffering agent is sodium bicarbonate. There is no evidence in the record that a composition meeting the ratio requirement without using bicarbonate as the buffering agent or meeting the range requirement of the currently amended scope . Please note, the buffering agents as described in the specification (pages 115-117) have different pH, ionic strength, buffering capacity, there is no evidence that all such broad range of basic compounds can form buffer. There is no description or operability supporting that the wide varieties of basic agent generically encompassed by the terms would all function in analogous manner in providing serum absorption or omeprazole stabilizing effect with the bicarbonates.

There is no range or guidelines as to what is the desired ratio of disintegrant in the instant invention. While the incorporation of distintegrant is conventional modification in the pharmaceutical composition art and can be derived by one having ordinary skill, the specific range finds no antecedent basis as to be considered being applicants' invention. Nor was any particular range enabled to entitle to such a claim.

Therefore, the instantly amended ranges are considered new matter.

Applicants argued that in sections [0571]-[0574] ranges of 27.27 and 45.45 were disclosed and one skilled in the art would be able to drive an amount based on the exemplified amount based on the type and efficacy of the disintegrant. Please note that the guidelines as set forth by the court is:

> *"The first paragraph of Section 112 of the Patent Act requires that a patent application include "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. §112, ¶ 1. "[T]o be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'. "*

See In re Wright, 999 F.2d 1557, 1561 [27 USPQ2d 1510] (Fed. Cir. 1993) (citing In re Vaeck, 947 F.2d 488, 495 [20 USPQ2d 1438] (Fed. Cir. 1991)); In re Wands, 858 F.2d 731, 736-37 [8 USPQ2d 1400] (Fed. Cir. 1988); In re Fisher, 427 F.2d 833, 839 [166 USPQ 18] (C.C.P.A. 1970)).

A survey of the specification evidenced that there is no "generic description" as to provide any Markush guidance on what are the elements being considered as "alternative equivalency" of the exemplified kind and quantity of disintegrant croscarmellose. There is no support on "any and all" known disintegrants would have the same *range* of efficacy in *weight base* within the range of 12-66 mg. Lacking of generic guidance in kind and quantity, the claims lack sufficient support for the scope of all "disintegrant". 112 first paragraph requires the specification itself to inform not for other to figure it out by themselves. In re Gardner 166 USPQ 138.

**3.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable

diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 237-289 are rejected under 35 U.S.C. 102(f) or (g) as being anticipated by Hall et al. US2005/0037070 or Olmstead et al. US 2005/0266071.

To the extend that the inventive concept containing a particular composition comprising omeprazole, bicarbonate buffer and distintegrant with an explicit range, it was explained supra that antecedent basis for such concept was not found. Therefore, claim 1 of Olmstead et al. '071 which reads on the instant newly amended claim 237-280 presentation dated Oct. 31, 2007, is considered prior art under 35 USC 102(g).

To the extend that the inventive concept containing particular amounts of omeprazole, bicarbonate and sodium croscarmellose i.e. examples I.A-I.G3 as delineated on page 8 of the remark filed Oct. 31, 2007, the two references disclosed specific compositions i.e. species that anticipated the broad claims while the species of the instant application did not contain the two species of the references (see Hall et al. '070 p.21, examples 4 and 5; see Olmstead et al. '071, p.22 table 2.A.1 and 2.A.2). Since species anticipates the genus, were applicants argued that the ranges finds antecedent basis thus supports the generic claims, the 102(f) and (g) issues must be resolved. Please note that the species of the two references always anti-dates the instant application since no such composition was disclosed, nor was any range concept finds description in the specification.

Applicants argued that the two references were filed after the effective filing date of the instant claims. Please note that, the species that anticipated the instant generic claims was "prior possession" to the instant application because such a species encompassed by the generic scope was not disclosed by the instant application and as explained supra that no generic concept supporting the instant generic scope was found. In addition, 102(f) or (g) do not required prior dating only "evidence" of possession by another.

**4.** Claims 237-289 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,489,364 in view of Jung et al. CA 128:261816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to prima facie obvious inclusion of

the croscarmellose sodium which has been well recognized in the art to be an conventional disintegrant (see US 4,639,458; 4,681,765; 4,904,477; 4,910,022; 5,256,699; 5,370,878; 5,861,172 etc. *references will not be listed on 892* i.e. per ponderous of evidence), and it is also known to be operable with omeprazole (see Choi et al. of record).

Claims 237-289 are rejected as being unpatentable over claims 18-56 of US 6,489,364 or claims 1-51 of US 6,699,885 or the claims are provisionally rejected over the copending claims 24-25, 32-36, 77-88, 90-100, 103-110 of SN 10/641,732, on the ground of nonstatutory obviousness-type double patenting. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to material being used in the issued claims or copending claims with prima facie obvious inclusion of a conventional disintegrant. The prima facie obvious material and method of using such prima facie obvious material should be bind together to prevent unreasonable multiple harassment based on the decision of In re Ochai. Please note that no restriction between the material and method of using the identical material was made. Therefore were the claims presented in a single application, they would be joined in issuance.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**5.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*
*July 8, 2009*

*Celia Chang*
*Primary Examiner*
*Art Unit 1625*